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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/646,035	08/22/2003	Gust H. Bardy	020.0337.US.CON	9276
49475	7590	01/11/2006	EXAMINER	
LAW OFFICES OF PATRICK J.S. INOUE			OROEZA, FRANCES P	
810 THIRD AVE			ART UNIT	
STE. 258			PAPER NUMBER	
SEATTLE, WA 98104			3766	

DATE MAILED: 01/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/646,035

Applicant(s)

BARDY, GUST H.

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 10/27/05 (Response).
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-54 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-54 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>7/25/05; 10/27/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

1. The Applicant at least amended the independent claims, hence the rejection of record is withdrawn and a new rejection established in the subsequent paragraph.

Claim Rejections - 35 USC § 103

2. Claims 1-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 6168563) in view of Levine (US 4852570).

Brown discloses a system for remotely regularly monitoring patients that combine medical device monitoring with query of the patients based creating a data baseline (abstract; col. 1 @ 29-64; col. 6 @ 4-7). The system includes a server (2018) /clearinghouse (54) with a database (2038), a remote clinician workstation (60), a remote programmable patient interface apparatus (58), modem (52) / communication network (2024), and at least one monitoring device for measuring a physiological condition and for transmitting the measurements to the apparatus (16, 20 and 22) (figs 1, 2, 12; col. 9 @ 20-32 and 42-52; col. 15 @ 40-47). The apparatus includes a display and buttons to enable the query (figs. 14-16; col. 25 @ 58 – col. 26 @ 36) or a speech synthesizer and a speech recognizer for audible queries (figs 24-26; col. 32 @ 12 – col. 33 @ 34). As an option, the display can be used with the microphone (2118) and speaker (2072) (col. 32 @ 14-22). A scripted program(s), read as the computer readable storage medium for performing the methods, are received from the server to control the interactions between the apparatus and the patient (col. 9 @ 30-32) to collect monitoring device measurements (2044), to communicate the queries, to receive the responses (2042) and to transmit the measurement data

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and responses to the server (col. 25 @ 43–49), hence providing feedback on 4 levels: patient status indicator and, potential medical concern to patient; potential medical concern to local medical personnel; and device reprogramming. The query and the physiological monitoring are contemporaneous (col. 30 @ 37–41). The system produces a patient report (2058) where device measurements are shown graphically and where query responses are included (figure 21). The reports can be standardized or customized using analysis to define the patient status for the healthcare profession (col. 7 @ 23–58). Multiple patients are managed with the system (col. 5 @ 66– col. 6 @ 7). Multiple measurements (including sibling and peer measurements) are obtained and compared (col. 15 @ 40–57).

As discussed in the previous paragraph of this action, Brown discloses the claimed invention except for the status indicator to recognize a trend in a patient indicating disease onset or disease progression and to determine whether medical intervention is necessary.

Levine teaches medical diagnosis using comparison of collected measures on a substantially regular basis to recognize a trend indicating disease onset in a patient for the purpose of determining whether medical intervention is necessary. It would have been obvious to one having ordinary skill in the art at the time of the invention to have recognized a trend in a patient indicating disease onset and to have determined the necessity of medical intervention in the Brown system in order to optimize the patient treatment so the patient's condition is cured, or at least the problem is arrested or neutralized (abstract; col. 1 @ 13–21; col. 2 @ 5–45; col. 7 @ 61 – col. 8 @ 43).

3. Claims 1-54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brown (US 6168563) in view of Iliff (US 6234964).

Brown discloses a system for remotely regularly monitoring patients that combine medical device monitoring with query of the patients based creating a data baseline (abstract; col. 1 @ 29-64; col. 6 @ 4-7). The system includes a server (2018) /clearinghouse (54) with a database (2038), a remote clinician workstation (60), a remote programmable patient interface apparatus (58), modem (52) / communication network (2024), and at least one monitoring device for measuring a physiological condition and for transmitting the measurements to the apparatus (16, 20 and 22) (figs 1, 2, 12; col. 9 @ 20-32 and 42-52; col. 15 @ 40-47). The apparatus includes a display and buttons to enable the query (figs. 14-16; col. 25 @ 58 – col. 26 @ 36) or a speech synthesizer and a speech recognizer for audible queries (figs 24-26; col. 32 @ 12 – col. 33 @ 34). As an option, the display can be used with the microphone (2118) and speaker (2072) (col. 32 @ 14-22). A scripted program(s), read as the computer readable storage medium for performing the methods, are received from the server to control the interactions between the apparatus and the patient (col. 9 @ 30-32) to collect monitoring device measurements (2044), to communicate the queries, to receive the responses (2042) and to transmit the measurement data and responses to the server (col. 25 @ 43–49), hence providing feedback on 4 levels: patient status indicator and, potential medical concern to patient; potential medical concern to local medical personnel; and device reprogramming. The query and the physiological monitoring are contemporaneous (col. 30 @ 37-41). The system produces a patient report (2058) where device measurements are shown graphically and where query responses are included (figure 21). The reports can be standardized or customized using analysis to define the patient status for the

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healthcare profession (col. 7 @ 23-58). Multiple patients are managed with the system (col. 5 @ 66- col. 6 @ 7). Multiple measurements (including sibling and peer measurements) are obtained and compared (col. 15 @ 40-57).

As discussed in the previous paragraph of this action, Brown discloses the claimed invention except for the status indicator to recognize a trend in the patient indicating disease onset or disease progression and to determine whether medical intervention is necessary.

Iliff teaches disease management using patient information accumulated over time to recognize a trend in a patient indicating disease progression for the purpose of determining whether medical intervention is necessary. It would have been obvious to one having ordinary skill in the art at the time of the invention to have recognized a trend in the patient indicating disease progression and to have determined the necessity of medical intervention in the Brown system in order to ensure an appropriate response when health changes are identified as critical points, so the predicted health decline is anticipated and appropriate intervention is supplied (abstract; col. 3 @ 10-18, 33-40; col. 3 @ 63 – col. 4 @ 2; col. 19 @ 29-45; col. 20 @ 54-61).

Statutory Basis

4. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Conclusion


Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Fran Oropeza whose telephone number is (571) 272-4953. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Robert E. Pezzuto can be reached on (571) 272-6996. The fax phone numbers for the organization where this application or proceeding is assigned is (571) 273-8300 for regular communication and for After Final communications.

Frances P. Oropeza
Patent Examiner
Art Unit 3762

FPO
1/7/06


Robert E. Pezzuto
Supervisory Patent Examiner
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